

Accountability through Regulation in Ontario's Medical Laboratory Sector

Réglementation visant l'obligation de rendre compte dans le secteur des laboratoires médicaux en Ontario



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Abstract

Although the use of performance indicators for the analytical (and highly measurable) phase of the medical laboratory process has had a long and successful history, it is now recognized that the value of a laboratory test is embedded in a system of care. This case study, using both documents and interview data, examines the approaches to accountability in the Ontario Medical Laboratory Sector, noting both the challenges and benefits. This sector relies heavily on the regulation instrument, including a requirement that all medical laboratories licensed by the provincial government must follow the guidelines set out by the Quality Management Program – Laboratory Services. We found the greatest challenges exist in the pre-analytical phase (where a large portion of total laboratory errors occur), particularly the interface between the laboratory and other providers.

Résumé

Bien qu'on utilise depuis longtemps les indicateurs du rendement dans la phase analytique (et fortement mesurable) des processus en laboratoire médical, il est maintenant reconnu que la valeur d'un essai en laboratoire est inhérente au système de soins. Cette étude de cas, qui repose sur des données recueillies dans la documentation et par entrevues, examine les démarches visant l'obligation de rendre compte dans le secteur des laboratoires médicaux en Ontario, en soulignant tant les défis que les avantages. Ce secteur est très axé sur la réglementation, notamment avec l'exigence selon laquelle tous les laboratoires médicaux ayant obtenu licence auprès du gouvernement provincial doivent suivre les directives établies par le Quality Management Program – Laboratory Services. Nous avons observé que les principaux défis se situent dans la phase préanalytique (où a lieu une grande partie des erreurs en laboratoire), particulièrement dans le rapport entre le laboratoire et les autres fournisseurs.

MEDICAL LABORATORIES PROVIDE OBJECTIVE DATA ESSENTIAL FOR DIAGNOSIS, monitoring and treatment of patients, as well as playing an important role in disease control and surveillance; the Ontario Auditor General estimated that about 80% of such data came from the Medical Laboratory Sector (MLS) in Ontario (Office of the Auditor General of Ontario 2007).

The laboratory process is highly complex; it begins with the ordering of the test by the healthcare provider and ends with the interpretation of a test result that has a significant impact on patient care (Gamble and Deber 2004; Plebani 2009, 2010). The three phases of laboratory process are identified as pre-analytical (e.g., test ordering, collection and transportation), analytical or technical (e.g., conducting the test) and post-analytical (e.g., interpretation of results and the significance for patient care). It has been reported that the percentage of total errors ranges from 46% to 68.2% in the pre-analytical phase and from 18.5% to 47% in the post-analytical phase (Plebani 2006: 750). As a result, performance measurement for the MLS usually will not involve a single metric but includes a variety of assessments and approaches that require a systems approach to encompass all phases in the laboratory process. Indeed, to measure performance, most jurisdictions, including Ontario, require medical laboratories to continuously develop and implement new performance indicators in response to a number of challenges, including the introduction of new and innovative complex testing procedures (e.g., genetic testing and molecular diagnostics) and technologies (e.g., multi-analytic tests versus single laboratory test, point-of-care testing [POCT]), different delivery models (e.g., rapid response laboratories, core laboratories) and increased volume of testing in response to the increased incidence and prevalence of chronic conditions. The use and type of performance indicators may vary with differences in the type of services delivered, incentive structures in place, technology used and the population being served.

Performance indicators serve a number of purposes including the documentation of quality, comparisons over time and across settings, assisting in priority setting, supporting accountability, regulation and accreditation and quality improvement (Lohr 1990). Approaches in the past to measure and monitor performance in the MLS have used quality control methods and quality assessments that are focused on the analytical phase of testing (Gamble and Deber 2004; Plebani et al. 2006), but quality assurance in this sector has been expanding to focus across all three phases.

Quality Management of Laboratory Services in Canada

A quality management program for laboratory services, including external quality assessment (EQA) and laboratory accreditation, was first introduced and implemented in Ontario to address many of the concerns listed above. Other provinces across Canada have also implemented the same program, either voluntarily or as a result of regulatory requirements (Ontario Medical Association 2012). This case study sought to identify the approaches to accountability in the Ontario MLS, focusing on Ontario's Quality Management Program – Laboratory Services (QMP-LS), and to determine stakeholder views on the challenges and benefits of the approaches currently in place to aid those seeking to improve the quality of laboratory services in other jurisdictions.

The interpretation and implementation of the requirements of the QMP-LS are left to the responsibility of each individual laboratory. Accordingly, we interviewed individuals responsible for both the interpretation and implementation of the QMP-LS requirements.

Methodology

Using a similar conceptual framework and methodological approach to the other articles in this volume (Deber 2014), we combined a document analysis with a series of 20 semi-structured interviews with key stakeholders from the MLS. Among the websites consulted for the document analysis were the Canadian Society of Medical Laboratory Science (CSMLS), College of Medical Laboratory Technologists of Ontario (CMLTO), IMSM Canada Ltd Ontario (for ISO 17025:2005 Laboratory Competence), Office of the Auditor General of Ontario, Ontario Society of Medical Laboratory Technologists, QMP-LS, Service Ontario E-Law and The Institute for Quality Management in Healthcare. The sample for the interviews included eight laboratory managers, five medical laboratory technologists (MLTs), three educators, two physicians, one participant from a professional organization and one administrator. Seventeen (85%) of the respondents were female and three (15%) were male. Three participants were from private for-profit laboratories, 14 were from the private not-for-profit laboratories, two were from public health laboratories and one was from a private not-for-profit professional organization representing the medical laboratory profession. Data triangulation of information collected from the documents and interviews was used to enhance validity by compensating for the fallibility of either method (Bickman and Rog 1998).

Ontario MLS

The majority of medical laboratory services in Ontario are publicly funded. As a result, medical laboratories are accountable to the government (who pays and regulates this sector), to citizens (who through taxation provide the funds for the delivery of services), to providers (who order the tests) and, ultimately, to patients (who are the recipients of care resulting from the test interpretation). The costs to provide individual laboratory tests are related to factors such as the volume of testing (e.g., high-volume routine testing may gain economies of scales), level of automation (e.g., totally automated laboratory testing system versus POCT) and the extent of the technical expertise (e.g., scientist, pathologist, technician, technologists) needed to conduct and interpret the tests; these cost differences may or may not be reflected in the fees paid.

Like other health services in Ontario, most laboratory services are delivered by the private sector (Marchildon 2013). The Ontario MLS can accordingly be categorized into four sub-sectors, based on their public–private ownership status: hospital-based laboratories (private not-for-profit), community-based laboratories (private for-profit investor-owned), laboratories found in physician offices (private for-profit small businesses) and public health laboratories (public). Although variability exists in terms of ownership and governing structures, costs, testing procedures and types of testing services delivered, all publicly funded medical laboratories in Ontario, with the exception of testing done in physician offices, must comply with the *Ontario Laboratory and Specimen and Collection Centre Licensing Act* (Government of Ontario 1990).

The most recent published estimates reported by the Office of the Auditor General of Ontario (2007) indicate that in the 2005/2006 fiscal year, the Ontario Ministry of Health and Long-Term Care (MOHLTC) spent \$1.4 billion on laboratory services, of which hospital laboratory expenditure was \$824 million, private sector laboratory spending was \$572 million and \$4.4 million were provided to the Ontario Medical Association (OMA) to operate quality assurance programs. It is unclear whether this estimate for private sector laboratories includes laboratory costs for testing conducted in physician offices. However, a 2005 report by the Auditor General of Ontario stated that for the 2003/2004 fiscal year, the Ontario government paid \$30.8 million to more than 750 physicians for laboratory testing (Office of the Auditor General of Ontario 2005).

Hospital-based laboratories are funded through the hospital's global budget, which, as noted, is almost entirely publicly funded. Ontario's community-based laboratories receive public funding based on fee-for-service and bill the Ontario Health Insurance Plan, which covers most physician services. Under the funding model at the time of writing, funding levels for these laboratories were capped. The cap for each community-based laboratory (and its market share) varies (personal communication with an owner from a private for-profit investor-owned laboratory). Community-based laboratories can perform testing above the approved cap, but do not receive any additional funding for this from public sources. Testing performed in physician offices is also reimbursed based on a fee-for-service, but there is no imposed cap for these laboratories. Private sources of funding include payment for services through private insurance

and out-of-pocket payment by individuals (e.g., prostate-specific antigen testing) or employers (e.g., drug testing of truck drivers).

There is widespread agreement in the literature that improvements in the quality of service provided by medical laboratories are desirable, and that not having the proper regulation, controls and quality management system in place has potentially jeopardized the delivery of quality, safe, timely and appropriate care (Chafe et al. 2009; Plebani 2009). This has been highlighted by a series of errors associated with testing, primarily but not exclusively related to pathology laboratories; these have led to provincial inquiries and identified a number of issues associated with laboratory quality. For example, the Cameron Inquiry investigated errors in hormone receptor testing in the Eastern Health region in Newfoundland and Labrador, and determined that there was failure and oversight at all levels, including the medical laboratory. As noted by Justice Cameron "...had proper quality assurance and control policies been put in place and had been followed, the problem with ER/PR (estrogen and progesterone receptors in breast cancer) testing would certainly have been discovered much earlier" (Cameron 2009). Similar problems have been identified in other provinces (British Columbia, Manitoba, Ontario, Quebec and New Brunswick). However, as stated by André Picard, health reporter for *The Globe and Mail*, "there are no national standards, standards vary from province to province and sometimes from one lab to the next." (Picard 2012).

The discussion that follows is based on data collected from documents and interviews relating to public health laboratories, hospital-based laboratories and community-based laboratories.

Role of Laboratory Licensing

The approaches to accountability are mixed, and all four approaches (financial incentives, regulation, information directed to potential users and reliance on professionalism/stewardship) identified by Deber (2014) are used to a varying extent in the MLS. The complexity of the relationship between the different approaches is articulated in this statement from a manager of a regional hospital-based laboratory:

We are accountable fiscally first to our executive vice president for maintaining a balanced budget ... accountability for performance to meet the anticipated customer demands and align ourselves with the strategic plan ... we are accountable through performance indicators which are chosen and monitored to ensure that we are meeting the performance of expectations of our customers and includes things like turnaround time and accuracy ... so from a patient safety point of view we have direct accountability to the medical director and from the operational piece around fiscal management and performance to the VP , we have a dual accountability.

However, regulation plays a major role in determining who is accountable, and for what, in the MLS sector. An educator from a medical laboratory science program noted:

Regulation is what really drives our business. You know we have the Ontario Laboratory Accreditation process and then there are also other regulations just for best practice, people are following and when you are a leading academic institution, you need to follow those, you need to be aligned with your peers.

In terms of “accountable to whom,” there are a number of different legislative structures and stakeholders, both within government and outside government, who play a key role in the regulation of the Ontario MLS. Key stakeholders include but are not limited to the Ontario MOHLTC, the CSMLS, the CMLTO and the OMA. These regulations affect the people who can work in the MLS, as well as the laboratories themselves.

The CSMLS is a national body responsible for the certification of MLTs and medical laboratory assistants/technicians (MLAs) who work in medical laboratories or specimen collection centres. Medical laboratory technology is a regulated profession under the *Ontario Regulated Health Professions Act* and the *Medical Laboratory Technology Act*. The CMLTO is the regulatory college for Ontario’s MLTs. However, MLAs are not regulated in Ontario and work under supervision to assist in a number of pre-analytical activities.

The MOHLTC, under the *Ontario Laboratory and Specimen and Collection Centre Licensing Act*, licenses and regulates Ontario’s medical laboratories (Government of Ontario 1990). This Act sets out the guidelines that are used to own, operate and license a specimen collection centre or a laboratory in Ontario. All public health laboratories, hospital-based laboratories, community-based laboratories and specimen collecting centres must be licensed and renewed annually. The application process involves paying the appropriate fee and providing the MOHLTC with relevant information, which includes details on a laboratory’s staff number, staff qualifications and laboratory equipment. The type of laboratory license determines what kind of tests the laboratory is licensed to perform. Note that under this Act, laboratory testing conducted in physician offices is not regulated.

Quality Management Program – Laboratory Services

In addition, other regulations mandate quality management, which is tied to accreditation. Regulation 682 in the *Laboratory and Specimen and Collection Centre Licensing Act* specifies that the OMA is the agency responsible to carry out a quality management program for the Ontario MLS. This program is called the Quality Management Program – Laboratory Services (QMP-LS) and is funded by the MOHLTC. QMP-LS is responsible for Ontario Laboratory Accreditation (OLA) and for EQA programs.

OLA accreditation is mandatory for all Ontario publicly funded laboratories (with the previously noted exception of laboratory services performed in physicians’ offices). Laboratories in New Brunswick and Newfoundland and Labrador are also required by provincial regulation to participate in OLA. There are 212 OLA-accredited laboratories operating in Ontario (<http://www.qmpls.org/LaboratoryAccreditation/AccreditedLaboratories.aspx>). The QMP-LS, through OLA, examines the quality of laboratory services using a management

process that includes all three analytical phases. The OLA accreditation is a rigorous exercise; laboratories are potentially examined on more than 500 requirements. As reported by the QMP-LS, the requirements are based on the International Organization for Standardization (ISO) standards for quality and competence (ISO 15189:2007), safety (ISO 15189:2007) and POCT (ISO 22870:2006), and on Canadian national standards requirements for safety (CAN/CSA-Z15190-05) and blood and blood components (CSA Z902-10). The standards are cross-referenced with Canadian statutes and regulations, provincial statutes and regulation and Health Canada. Laboratories accredited by OLA demonstrate compliance with international standards for quality and competence.

If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A panel then determines if the laboratory meets the criteria for an accreditation certificate. Failure to meet accreditation standards may result in warnings, loss of license and, subsequently, loss of public funding.

The purpose of the EQA program is to assess laboratory test performance and to provide education. Patient/simulated specimen samples and challenge surveys are used to examine the analytical processes of individual laboratories and to measure the effectiveness of different procedures and analytical kits supplied by manufacturers. For example, the identification of unsatisfactory performance by EQA at a single laboratory may indicate that at this laboratory, additional training and/or retraining is required. However, if through EQA unsatisfactory performance is identified at several different laboratories for the same procedure, this may indicate a problem with the method and/or kit being used for testing. Included in the EQA programs are measures to address the pre- and post-analytical stages of testing using patterns-of-practice surveys and questionnaires. Laboratories demonstrating unsatisfactory performance are required to implement corrective action; if the laboratory fails to do so, it may be considered non-proficient and referred to the MOHLTC for further remedial action that may include suspension of its ability to do testing. In addition to the EQA program, laboratories usually perform internal quality assurance and participate in other quality and accreditation programs (e.g., College of American Pathologist Accreditation) offered by organizations other than QMP-LS.

Views on QMP-LS Program

One of the unintended benefits of the QMP-LS program noted by our respondents is that it has raised awareness of the role of the medical laboratory profession. As articulated by a manager of a hospital-based laboratory:

I think what it (OLA) has done is it has raised a different level of awareness for our profession and on some level has put us on the map in terms of a more cutting-edge approach to regulatory standards.

One director of laboratory services spoke about the strengths of the QMP-LS program and made reference to the fact that OLA and EQA are based on international standards:

Everything that we do is measured against a set of standards that are internationally recognized and are based on best available evidence that the international committee through international standardization (ISO) can achieve ... So OLA and EQA themselves are both accountable to a higher authority, which tells us whether or not we are meeting the standards for organizations that do proficiency testing and accrediting bodies. So we too walk the walk of accountability at QMP-LS. There are not many examples to match the degree of accountability that you see in diagnostic laboratory services.

The strengths of OLA and the QMP-LS overall are further illustrated by another hospital-based laboratory manager who has experience as an assessor for OLA:

I think in general it is making everyone rise to a level of quality that is admirable and I really think Ontario is further ahead.

When asked if the accreditation process actually helped their organization accomplish its goals, one director of a community-based laboratory stated:

Yes, for a number of very simple reasons. We are a market-driven, employer-driven institution and that is one of our primary goals and our students could not work without this program being accredited. So it was kind of, we had to be accredited for our students to successfully graduate and enter the workforce.

This statement illustrates that the goals of the MLS sector go beyond producing quality services to include a quality-training environment for students and to maintain a competitive edge in the marketplace.

A community-based laboratory manager stated OLA's strength lies in:

Ease of measurement in terms of faster turnaround time; more cost effective; getting frontline workers to buy into the plan and feedback from physicians and patients.

Another manager from a hospital-based laboratory commented:

One of the strengths was the level of flexibility that was built in the process especially when it came down to interpreting the standards ... and to be able to customize for your organization to meet OLA standards.

However, not all respondents shared this view. In fact, the ability to interpret the standards was seen as challenging especially for those laboratories with smaller fiscal budgets. For example,

Accreditation is very expensive. Our accreditation fees on an annual basis are ten thousand dollars, because it is a very expensive process and we have to support it. It used to come out of our Med Lab budget directly, which you know meant it had a significant impact on our operational costs.

One hospital-based MLT indicated:

I found them (OLA requirements) very, very difficult to interpret. To know exactly the depth and what exactly the documentation was looking for.

A manager of a large regional hospital-based laboratory indicated:

When people have the appreciation of the why, and sometimes when you are dealing with a large number of regulatory requirements, some of them don't always make sense to the people that have to implement ... I struggle with that sometimes with the standards but overall, really at the end of this, the intent is to have a safe system.

Another respondent from a public health laboratory shared a similar view:

I would say that there are probably some grey areas ... their regulations may be a little stringent.

One manager from a hospital-based laboratory voiced the organization's concern with preparation for OLA accreditation:

The Ontario Laboratory Accreditation ... 502 regulations there for effective practice for all the testing that goes on, the reporting right from pre-analytical to post-analytical covers the entire spectrum of what and how, really they don't tell you how, but what you have to do in order to become an accredited facility, and we are beholden with that because without accreditation we don't get our license to perform testing.

One manager from a hospital-based laboratory shared a personal view:

This is my own personal experience and not necessarily in this organization but I have encountered elsewhere where the sole focus has been so much on the regulatory requirement that all the rest of the things are forgotten. So, it [OLA] in some ways does not allow the innovation or the creativity that can happen when people don't have to focus so much on that within their own job roles.

Overall, those interviewed were very supportive of the QMP-LS program and believed that through regulation, the MLS is able to maintain quality and safeguards to identify areas of unsatisfactory performance. Considering the contribution the MLS makes to patient diagnosis, treatment and monitoring, having the appropriate safeguards in place was seen to be important.

While some respondents appreciated the flexibility of the program, which allowed the ease of implementation of the OLA requirements, others were not convinced and experienced difficulties interpreting the standards as applied to their laboratory. This was especially evident when individuals commented on the pre-analytical phase. For example, when referring to OLA, one MLT stated:

I was thinking about how it doesn't really help us with the front end, pre-analytical quality. We are still lacking in the Phlebotomy area with quality and quality assurance as far as our direct patient contact ... do you know where I am going with that? We still need to work on some out-of-the-lab things ... but because it is outside the lab I believe we have a lot more to work on towards that.

A physician from a hospital-based laboratory indicated:

... the accountability of lab tests, part of it depends on the physicians. So, I don't think there was enough physician education to tell them when a test needs more work or what tests need more time, which tests cost more ... they just order them and I feel that really there is no accountability for physicians ordering the tests. They just go down to requisitions and just order whatever they feel like and sometimes they are not what are needed. In the hospital, we can control them a little bit more, but in other labs they just do what tests are ordered and it could be part of our training.

Discussion

Although all four approaches to accountability described in this issue (Deber 2014) are used in the Ontario MLS, the main approach to accountability is regulation. Regardless of ownership structure, all publicly funded medical laboratories (with the exception of laboratories found in physician offices) must comply with regulation as mandated by the Ontario provincial government to maintain an operating license to conduct testing. This approach has been in place for more than 40 years (Gamble and Deber 2004). However, previous quality controls and quality assessments were primarily focused on the analytical phase of the laboratory process. As the conceptual framework would predict, this is related to the high measurability of this phase, which lends itself to the use of both external and internal quality controls and quality assurance programs to measure the reliability, validity and turnaround times of test results.

However, our respondents stressed that this is incomplete; the true value of a laboratory test result is more fully appreciated when it is embedded in a system of care. The complexity

("embeddedness") of the goods and services being produced can also affect performance monitoring. Illustrative of this point is the investigation of the series of events that led to the Walkerton, Ontario water crisis, which resulted in several deaths and illnesses due to contaminated drinking water (O'Connor 2002). The Walkerton Inquiry demonstrated that although the tests themselves were often properly conducted, a series of errors in the pre-analytical and post-analytical stages contributed to the failure of the Walkerton Public Commission to notify Walkerton citizens and the appropriate government officials of the contaminated water.

Key to the QMP-LS is the flexibility of the program to allow individual laboratories to implement the processes to address OLA requirements. This is not surprising, as the type of testing and the automation used for testing vary across the MLS. However, one constant variable stands out – healthcare providers outside of the laboratory are the ones responsible for test ordering and for interpreting the meaning of the test result(s) for the patient. The quality of medical laboratory services directly impacts the patient but also impacts the quality of care provided by other frontline providers, who order the tests for diagnosis, treatment and monitoring. Clearly the interface between the laboratory and other providers is an important aspect of delivering quality laboratory services in the pre-analytical phase, and one which is not always captured in the approaches to accountability being used.

Conclusion

This case study provides an example of a highly measurable service, which seems at first glance to be easily monitored through regulation. However, challenges do exist with implementing laboratory regulation. The laboratory is not a stand-alone entity but is an integral part of the healthcare continuum. As such, ensuring quality in the MLS requires collaboration with other providers outside of the laboratory. Monitoring laboratory performance by solely focusing on the analytical phase is incomplete; it is important to also address and prevent errors in the pre- and post-analytical phases. Further investigation is needed to better understand the interface between the laboratory and healthcare providers outside of the laboratory working in different healthcare sectors (e.g., primary care versus institutional care) in order to develop strategies to inform the implementation of OLA requirements, particularly in the pre-analytical phase. Another emerging issue is the growing reliance on POCT performed by providers outside of the laboratory at the bedside; these are not always captured by existing accountability frameworks.

Questions of who is responsible for monitoring performance and how this will be done need to be addressed. Our results argue that coordination is required between the laboratory and the bedside providers for the monitoring of quality control compliance and operator performance levels. This also presents issues in how to deal with cross-sectoral coordination, particularly when actors in one sector cannot control the behaviour of those in other sectors. Improving quality in the Ontario MLS will ultimately require working with other providers to develop strategies and processes to improve performance measurements and to enhance accountability.

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